United States District Court Southern District of Texas

ENTERED

March 30, 2023 Nathan Ochsner, Clerk

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF TEXAS GALVESTON DIVISION

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§ CIVIL ACTION NO. 3:22-cv-00290
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MEMORANDUM AND RECOMMENDATION

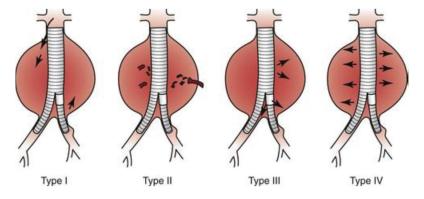
Pending before me is a Motion to Dismiss filed by Defendants Endologix, Inc. ("Endologix"), Endologix LLC, and Deerfield Management Company, LP ("Deerfield"). Dkt. 30. Having reviewed the briefing, the record, and the applicable law, I recommend that the motion be granted in part and denied in part.

BACKGROUND

Plaintiff Dwight Briggs ("Briggs") suffers from an aortic arterial aneurysm. "An aneurysm occurs when an artery wall weakens, which allows the artery to abnormally balloon or widen." Dkt. 21 at 3. "An aortic arterial aneurysm ('AAA') is a serious medical condition because a rupture of the aortic artery can cause fatal internal bleeding." *Id.* To prevent a rupture, patients like Briggs "may require surgery to repair, treat, and/or reinforce the artery wall." *Id.* at 3–4. "Implantable aneurysm repair grafts are a type of medical device that . . . function similar to a hose inserted into a damaged artery, which permits blood to flow through the 'hose' thereby avoiding the damaged portion of the artery." *Id.* at 4. "A surgeon implants an aneurysm repair graft device by inserting the device through an artery in the patient's leg and threading it up into the aorta/aneurysm." *Id.* As with any surgery, there are risks attendant to an aneurysm repair. One of those attendant risks is an endoleak. An endoleak is "when blood continues to remain or flow into the aneurysm cavity after the endovascular repair." *Id.*

There are four types of endoleaks, ranging from type I-IV. Type I endoleaks occur when there is a gap between the repair graft and the vessel wall that allows blood to flow into the aneurysm cavity. Type II endoleaks occur when blood from a collateral vein flow[s] into the aneurysm cavity. These are the most common type[s] of endoleak and are typically considered to be benign and are not a result of a defect in the graft. Type III endoleaks are attributed to device failures and occur when there is either a separation between the graft components (Type IIIa) or when there is a tear or hole in the graft material (Type IIIb). Type III endoleaks can result in aneurysm expansion and rupture. For this reason, Type III endoleaks require urgent or emergency medical attention. Type IV endoleaks occur when blood flows through the pores of the graft material and often resolve without intervention.

Id. at 4–5. The Second Amended Complaint contains this handy diagram, which visually depicts the difference between Type I-IV endoleaks:



Id. at 5.

On December 20, 2016, Briggs had surgery to repair an AAA. His surgeon selected an implantable Ovation iX stent graft ("the device") manufactured by Endologix for the repair. "The device was intended to treat AAAs by providing a new path for the blood to flow so it does not fill and expand the aneurysm." *Id.* at 11. Briggs's surgery was unremarkable, but about a month after the surgery, one physician told Briggs that he "had a 'small type II endoleak." *Id.* at 6. One month later though, a different physician told Briggs "that he had no endoleak at all." *Id.* Briggs acknowledges that "conflicting diagnoses would [normally] cause a patient to be immediately concerned about the status of the device." *Id.* Yet, Briggs asserts that he was "continuously and repeatedly told from 2016 to 2020 that there was 'no problem' with [Briggs's] device and that any Type II endoleak, if it existed,

would correct on its own." *Id.* On October 7, 2020, however, a third physician diagnosed Briggs "with a Type III endoleak because of a 'material weakness' in the graft material" of his Ovation iX stent graft. *Id.* Briggs has since undergone two stent repair procedures to repair the Type III endoleak and will need routine computed tomography ("CT") angiograms every six months to monitor the leak.

Briggs and his wife, Konnie Briggs, instituted suit in Texas state court alleging claims of strict liability for manufacturing, design, and marketing defects ("failure to warn"); negligent design, manufacturing, production, preparation, installation, assembly, testing and/or inspection of the subject device; negligent failure to warn/breach of duty to warn plaintiff of defective condition of subject device; negligence; negligence per se; fraud; marketing defect; and loss of consortium. Plaintiffs allege that Briggs's two procedures, dozens of doctor visits, and the need for CT angiograms every six months are the "direct and proximate result of the failed and defective Endologix device." *Id.* at 8. Defendants removed the case to federal court and moved to dismiss. While Defendants' first motion to dismiss was pending, Plaintiffs amended their complaint. The operative pleading is thus the Second Amended Complaint (Dkt. 21).

With regard to the Second Amended Complaint, Defendants contend that Plaintiffs' claims against all Defendants must be dismissed because: (1) they are barred by Texas's two-year statute of limitations for strict liability and negligence claims; (2) they were discharged during Endologix's Chapter 11 bankruptcy proceeding; (3) they are expressly and impliedly preempted under the Medical Device Amendments to the Federal Food Drug and Cosmetic Act; and (4) Plaintiffs have failed to allege sufficient facts to give rise to a plausible lawsuit. Once briefing was completed, I held a hearing on Defendants' motion. The parties were represented by competent and professional counsel who very helpfully narrowed the issues for me. During that hearing, Plaintiffs' counsel explicitly conceded that: (1) Plaintiffs do not have claims for fraud, negligence per se, or design defect; and

(2) Plaintiffs do not have any claims against Deerfield.¹ Plaintiffs' counsel also acknowledged that the many negligence claims are duplicative. Accordingly, the only claims that Plaintiffs continues to assert after the hearing are strict liability and negligence claims for failure to warn and manufacturing defect, and loss of consortium. I will now address each of Defendants' arguments for dismissal in turn.

LEGAL STANDARD

Rule 12(b)(6) allows dismissal if a plaintiff fails "to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). The United States Supreme Court has emphasized that the complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Rule 8 "does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 555). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (quoting *Twombly*, 550 U.S. at 556). Ultimately, a Rule 12(b)(6) motion to dismiss "is viewed with disfavor and is rarely granted." *Turner v. Pleasant*, 663 F.3d 770, 775 (5th Cir. 2011) (quotation omitted).

¹ Even without these concessions, I would have dismissed each of these claims. I would dismiss Plaintiffs' fraud claim because Plaintiffs fail to plead fraud with particularity. *See* FED. R. CIV. P. 9(b). I would dismiss Plaintiffs' negligence per se claim because Plaintiffs fail to allege a causal nexus between the violation of a specific statute or ordinance and Briggs's injury. *See Moughon v. Wolf*, 576 S.W.2d 603, 604 (Tex. 1978). I would dismiss Plaintiffs' design defect claim because they fail to allege a safer alternative design that existed *at the time Briggs's graft was implanted. See Rodriguez v. Gilead Scis., Inc.*, No. 2:14-CV-324, 2015 WL 236621, at *3 (S.D. Tex. Jan. 16, 2015) (collecting cases). Finally, I would dismiss Plaintiffs' claims against Deerfield because there are no allegations of wrongdoing concerning Deerfield in the Second Amended Complaint.

ANALYSIS

A. BRIGGS FAILS TO STATE A MANUFACTURING DEFECT CLAIM

Under Texas law, when a plaintiff alleges a defective product, "whether a plaintiff seeks recovery because of negligence or a theory of strict liability in tort, the burden is on the plaintiff to prove that the injury resulted from a defect in the product." Ford Motor Co. v. Miles, 141 S.W.3d 309, 315 (Tex. App.—Dallas 2004, pet. denied). "A manufacturing defect exists when a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous." Cooper Tire & Rubber Co. v. Mendez, 204 S.W.3d 797, 800 (Tex. 2006) (quoting Ford Motor Co. v. Ridgway, 135 S.W.3d 598, 600 (Tex. 2004)).² "[A] touchstone of a manufacturing defect claim is proof that the allegedly defective product differs from other products in the same product line." Casey v. Toyota Motor Eng'g & Mfg. N. Am., Inc., 770 F.3d 322, 329 (5th Cir. 2014). In other words, to adequately allege a manufacturing defect, Plaintiffs "must show that the [Ovation iX stent graft used in Briggs's surgery] differs from the [Oviation iX stent grafts] that [Endologix] produced in the same time period and [that were implanted] in other [patients]." Id. Plaintiffs here allege:

The Ovation iX device at issue and its various component parts were in a defective and unreasonably dangerous condition at the time they left the hands of Defendant Endologix in that it deviated from product specifications and/or applicable federal requirements for these medical devices because of the use of defective or inadequate materials of the graft component adjacent to the polymer fill channel, posing a serious risk of injury, such as a Type III endoleak, and death.

Dkt. 21 at 16-17.

This conclusory assertion is insufficient to plausibly allege a manufacturing defect under Texas law. To start, Plaintiffs do not identify which "product

² To succeed on a manufacturing defect claim, a plaintiff must also "prove that the product was defective when it left the hands of the manufacturer and that the defect was a producing cause of the plaintiff's injuries." *Cooper Tire & Rubber*, 204 S.W.3d at 800. I do not discuss these elements here because Plaintiffs' failure to allege a manufacturing defect is fatal to their manufacturing defect claims.

specifications and/or applicable federal requirements" *Briggs's device* deviated from that rendered his device defective. Rather, Plaintiffs appear to hang their hat on a Class I recall of the Ovation iX stent graft. But the recall applied to the entire Ovation iX product line that was manufactured as designed. Plaintiffs never allege that the Ovation iX stent graft that Briggs received differed from its intended design or from other Ovation iX stent grafts. Accordingly, Plaintiffs do not allege a manufacturing defect. See Funk v. Stryker Corp., 631 F.3d 777, 782 (5th Cir. 2011) (finding plaintiff's complaint "impermissibly conclusory and vague [where] it does not specify the manufacturing defect; nor does it specify a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury[; n]or does the complaint tell us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process"); see also Fearrington v. Bos. Sci. Corp., 410 F. Supp. 3d 794, 803 (S.D. Tex. 2019) ("Plaintiff has not alleged in any detail the [product's] intended designs or specifications, how their manufacture deviated from those designs or specifications, or how such a deviation caused the alleged susceptibility once within the body. Plaintiff's manufacturing defect allegations are therefore impermissibly conclusory and vague, and Plaintiff has not properly stated a claim under Twombly and Igbal under either Texas or Florida state law."). Because Plaintiffs do not allege a manufacturing defect, they cannot plausibly state a manufacturing defect claim. Plaintiffs' manufacturing defect claim should be dismissed.3

B. Briggs's Failure to Warn Claim Is Preempted

I will assume, *arguendo*, that Plaintiffs adequately allege a failure to warn claim.⁴ Even so, such a claim is clearly preempted by § 360k of the Medical Device Amendments of 1976 ("MDA").

³ I do not reach Endologix's arguments regarding preemption of the manufacturing defect claim because, preempted or not, Plaintiffs do not plausibly state such a claim.

^{4 &}quot;To state a plausible claim, Plaintiff[s] must plead facts that would show:

Section 360k provides as follows:

Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
- (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). Under this statutory framework, "a medical device manufacturer is protected from liability under state-law tort claims related to a defective or dangerous device to the extent that the manufacturer has complied with federal statutes and regulations." *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 767 (5th Cir. 2011) (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)). But "when the claim is based on the manufacturer's violation of applicable federal *requirements*," then the "manufacturer is *not* protected from state tort liability." *Id.* (emphasis added). The operative word in that sentence is "requirements." If a state-law tort claim "parallels" a federal requirement, then a state-law tort claim based on a violation of that federal requirement is not preempted. *See Riegel*, 552 U.S. at 330 ("[Section] 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case

⁽¹⁾ A risk of harm inherent in the product or which may arise from the intended or reasonably anticipated use of the product;

⁽²⁾ the product supplier actually knew or should have reasonably foreseen the risk of harm at the time the product was marketed;

⁽³⁾ the product contains a marketing defect;

⁽⁴⁾ the absence of a warning renders the product unreasonably dangerous to the ultimate user or consumer of the product; and

⁽⁵⁾ the failure to warn must constitute a causative nexus in the product user's injury." *Fearrington*, 410 F. Supp. 3d at 801 (citing *Wright v. Ford Motor Co.*, 508 F.3d 263, 274–75 (5th Cir. 2007)).

'parallel,' rather than add to, federal requirements."). But if a state-law tort claim *adds* to or *differs* from a federal requirement, then it is preempted by federal law. *See Hughes*, 631 F.3d at 768 ("[S]tate common-law causes of action . . . cannot vary from federal requirements pursuant to § 360k."). Thus, to determine whether Plaintiffs' claim is preempted, I must look to see whether Plaintiffs have alleged the violation of a federal requirement that parallels their failure to warn claim under Texas law.

Relevant to their failure to warn claim, Plaintiffs allege that "after receiving information concerning the increased incidence of Type III endoleaks because of a material weakness in the Ovation iX device, Endologix failed to submit a [Premarket Approval ("PMA"] supplement to adequately apprise [Briggs] and his doctors of the increased risk of Type III endoleaks." Dkt. 21 at 14. This allegation is insufficient to state a parallel claim because, as Plaintiffs acknowledge, "a medical device manufacturer *may* submit a PMA Supplement to change a device's warning without prior FDA approval." *Id.* (citing 21 C.F.R. § 814.39(d)(2)) (emphasis added). Critically, it is not a *requirement* for a manufacturer to submit a PMA Supplement. Because there is no federal requirement for Endologix to submit a PMA Supplement to revise its label, "Plaintiffs cannot allege [Defendant]'s failure to submit a PMA supplement to the FDA as the basis for their label-based failure to warn claims." *In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig.*, 537 F. Supp. 3d 679, 710 (D.N.J. 2021) (*In re Allergan*).

Plaintiffs also advance a less-than-explicit argument that Endologix should have used the Changes Being Effected ("CBE") process to updated the device's warning. *See* Dkt. 21 at 32. The "CBE exception allows a manufacturer to add or strengthen a contraindication, warning, or precaution without pre-approval from the FDA." *In re Allergan*, 537 F. Supp. 3d at 709 (cleaned up); *see also* 21 C.F.R. § 814.39(d)(1) ("After FDA approves a PMA, any change described in paragraph (d)(2) of this section to reflect newly acquired information that enhances the safety of the device or the safety in the use of the device *may* be placed into effect by the

applicant."). In other words, the CBE process allows a manufacturer to change a device's warnings without first submitting a PMA supplement. But this is also not a requirement, and an allegation that a manufacturer should have utilized the CBE process to strengthen its warnings is not an allegation that the manufacturer has failed to comply with any FDA requirement. As the *In re Allergan* court explains:

Though the CBE process allows [a device manufacturer] to update the label of its implants, [the manufacturer] is not obligated to do so, because the CBE process is not mandatory. However, Plaintiffs' label-based failure to warn claims would require [the manufacturer] to update warnings on the implants' label. This amounts to a state law duty that differs from or adds to the federal requirements in the PMAs, which triggers express preemption.

In re Allergan, 537 F. Supp. 3d at 709. In other words, Plaintiffs' insinuation that the device was misbranded under 21 U.S.C. § 352(a)(1) because Endologix did not utilize the CBE process (see Dkt. 21 at 32–33) is an argument that would impose an additional requirement on manufacturers that does not currently exist under federal law.

Plaintiffs' reliance on *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011) is unavailing. To start, the Fifth Circuit in *Hughes* held that the plaintiff's "products liability claim for failure to provide adequate warnings or instructions communicating dangers associated with the [device]" was "expressly preempted" to the extent that it "would question the sufficiency of the FDA-approved labeling, warnings, and instructions for [the device] or require [the manufacturer] to have included different warnings, labels, or instructions with the device." 631 F.3d at 768–69. The Fifth Circuit did allow the failure to warn claim in *Hughes* to proceed, but *only* because the claim was "predicated on [the manufacturer]'s failure to report 'serious injuries' and 'malfunctions' of the device as required by the applicable FDA regulations." *Id.* at 769. But here, Plaintiffs do not allege that Endologix failed to report serious injuries or malfunctions as required by the FDA.

Rather, Plaintiffs allege:

Pursuant to federal law, the Ovation system's Conditions of Approval required Endologix to create and provide a clinical update to physicians at least annually. In addition to other information, this update was specifically required to provide physicians relevant information from Endologix's commercial experience (adverse event reporting). Upon information and belief, Endologix failed to adequately comply with these federal requirements and instead attempted through numerous methods to conceal in its annual clinical update to physicians the increased risk of Type III endoleaks or other similar failures of the Ovation iX device caused by the material weakness in the device that Endologix eventually admitted to.

Dkt. 21 at 14–15. Critically, this allegation *acknowledges* that Endologix *provided* annual clinical updates to physicians. As such, Plaintiffs cannot (indeed, do not) allege that Endologix failed to comply with this requirement. Plaintiffs' allegation that Endologix "failed to *adequately* comply with these [unspecified] federal requirements" is conclusory. *Id.* at 15 (emphasis added).⁵ The conditions of approval that Plaintiffs reference—from a document that *Plaintiffs* introduced into the record—plainly state what is required to be provided in the annual clinical update to physicians. *See* Dkt. 14 at 51. Alas, Plaintiffs do not state what information that was required in the annual clinical update was not provided to physicians. Plaintiffs' allegation that Endologix "attempted through numerous methods to conceal [information] in its annual clinical update to physicians," Dkt. 21 at 15, is an allegation of fraud that requires far more particulars than Plaintiffs have provided. *See* FED. R. CIV. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.").

Finally, Plaintiffs' allegation that Endologix violated 21 C.F.R. § 820.100(a) and 21 C.F.R. § 812.140(b)(1), even if true, do not give rise to a failure to warn claim. The former of those requirements, 21 C.F.R. § 820.100(a), pertains to

⁵ Plaintiffs' allegation that "[i]f Endologix had . . . timely provided an annual update prior to Mr. Briggs receiving Endologix's defective product on December 20, 2016, Mr. Briggs and his physicians . . . would not have used [the device]," Dkt. 21 at 15, is also conclusory. There is no allegation in the complaint that Endologix did not timely provide an annual update.

current good manufacturing practices and has no connection to a failure to warn claim.⁶ The latter, 21 C.F.R. § 812.140(b)(1), deals with sponsor⁷ records and—absent some other allegation or explanation—also has no connection to a marketing defect/failure to warn claim. Briggs cannot just pick a federal requirement out of a hat—there must be a causal connection between the federal requirement that was allegedly violated and the state-law tort claim. *See Bass v. Stryker Corp.*, 669 F.3d 501, 517 (5th Cir. 2012) (A state-law tort claim "is not preempted if the plaintiff alleges that the defendant violated federal requirements and can ultimately show a causal link between the violation and the [state-law tort claim]."). Because Plaintiffs fail to allege the violation of any federal *requirement* that is causally connected to their failure to warn claim, that claim is preempted and should be dismissed.

C. KONNIE BRIGGS'S LOSS OF CONSORTIUM CLAIM SHOULD BE DISMISSED

Konnie Briggs's loss of consortium claim is a derivative claim that rises, or falls, with her husband's claims. *See Reed Tool Co. v. Copelin*, 610 S.W.2d 736, 738 (Tex. 1980) ("In holding the suit was derivative, we acknowledged that the wife, as a prerequisite to recovery, must establish the tortfeasor's liability for her husband's physical injuries."). Because I have already found that Briggs fails to state a claim on which relief can be granted, there is no claim from which Konnie Briggs's loss of consortium claim can derive. Accordingly, that claim should be dismissed.

⁶To the extent a violation of 21 C.F.R. § 820.100(a) is relevant to Plaintiffs' manufacturing defect claim, Plaintiffs fail to articulate the violation or to explain how such a violation supplies a causal nexus to their claim. Indeed, their only allegation concerning Endologix's violation of this regulation is the following statement: "For example, on September 2014, Endologix was cited for violating 12 C.F.R. § 820.100(a) because their 'procedures for corrective and preventative actions had not been adequately established." Dkt. 21 at 12. But Plaintiffs never allege *what* procedure(s) had not been adequately established, and they certainly do not allege how the failure to establish such procedure(s) is related to their claim.

⁷ "Sponsor means a person who initiates, but who does not actually conduct, the investigation, that is, the investigational device is administered, dispensed, or used under the immediate direction of another individual." 21 C.F.R. § 812.3(n).

D. PLAINTIFFS SHOULD NOT BE PERMITTED TO AMEND THEIR COMPLAINT

Plaintiffs originally filed this lawsuit in state court. After the case was removed to federal court, Plaintiffs filed an Amended Complaint. A few months later, Plaintiffs filed a Second Amended Complaint. Now, Plaintiffs conclude their response to Defendants' Motion to Dismiss with a cursory request for leave to amend their complaint yet again in the event I find the latest pleading insufficient to pass muster under Rule 12(b)(6).

Although district courts "should freely give leave [to amend] when justice so requires," FED. R. CIV. P. 15(a)(2), leave to amend is by no means automatic. *See Avatar Expl., Inc. v. Chevron, U.S.A., Inc.*, 933 F.2d 314, 320 (5th Cir. 1991). As the Fifth Circuit has explained on numerous occasions, the ultimate decision to grant or deny a motion to amend rests within the sound discretion of the trial judge. *See id.* When exercising its discretion to allow or deny leave to amend, the district court can consider a number of factors, such as "the futility of amending, the party's repeated failure to cure deficiencies by previous amendments, undue delay, or bad faith." *United States ex rel. Marcy v. Rowan Cos.*, 520 F.3d 384, 392 (5th Cir. 2008).

Plaintiffs provide no basis or detail for the requested amendment. In an ideal world, Plaintiffs would have provided me with a proposed amended complaint to review. Nonetheless, their "failure to attach a copy of the proposed complaint is not, on its own, fatal to a motion to amend." *Peña v. City of Rio Grande City*, 879 F.3d 613, 618 (5th Cir. 2018). What does, however, doom Plaintiffs' request to amend is their failure to apprise me of what additional facts they would include in a Third Amended Complaint. "[A] bare bones motion to amend remains futile when it fails to apprise the district court of the facts that [Plaintiffs] would plead in an amended complaint." *Edionwe v. Bailey*, 860 F.3d 287, 295 (5th Cir. 2017) (cleaned up). Because Plaintiffs have failed to explain what facts would be included in yet another amended pleading, their latest request to amend should be denied as futile. *See Rombough v. Bailey*, 733 F. App'x 160, 165 (5th Cir. 2018) ("[Plaintiff]

failed to apprise the court of the facts she would plead in her amended complaint; therefore the district court did not err when it denied her motion to amend as futile."). Moreover, there is no reason to believe that any amended pleading could overcome the preemption defense, which I have found to be meritorious. Accordingly, Plaintiffs' request to file a Third Amended Complaint is denied.

CONCLUSION

For the reasons stated above, I recommend that Defendants' Motion to Dismiss (Dkt. 30) be **GRANTED**.

The Clerk shall provide copies of this Memorandum and Recommendation to the respective parties who have 14 days from receipt to file written objections under Federal Rule of Civil Procedure 72(b) and General Order 2002–13. Failure to file written objections within the time period mentioned shall bar an aggrieved party from attacking the factual findings and legal conclusions on appeal.

SIGNED this with day of March 2023.

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ANDREW M. EDISON

UNITED STATES MAGISTRATE JUDGE